

Office of Regulatory Management
Economic Review Form

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-90
VAC Chapter title(s)	Disease Reporting and Control Regulations
Action title	COVID-19 Emergency Update
Date this document prepared	August 11, 2022

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> <p>• Add Coronavirus Disease 2019 (COVID-19 or SARS-CoV-2) to the disease lists in 12VAC5-90-80. Direct Costs: \$0</p> <p>Direct Benefits: Adds clarity that COVID-19 is a separate reportable disease from “coronavirus, severe” and that it is no longer rapidly reportable.</p> <p>• Remove the requirement to report negative COVID-19 test results. Direct Costs: Potentially minor costs to change electronic reporting system settings.</p> <p>Direct Benefits: Potentially significant cost savings for persons that do not have electronic laboratory reporting in place as this will greatly reduce the volume of reports that need to be submitted.</p> <p>• Include hospitalization status in the fields that are required to be reported by physicians and directors of medical facilities. Direct Costs: Potentially minor costs to change fields included in electronic reporting system settings.</p> <p>Direct Benefits: \$0</p> <p>• Clarifies that all entities with a CLIA waiver, not just pharmacies, are considered a laboratory director as it relates to this regulatory chapter. Direct Costs: \$0</p> <p>Direct Benefits: Provides clarity for regulated entities.</p>
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	<ul style="list-style-type: none"> • Clarifies the electronic methods available for laboratory reporting. Direct Costs: \$0 <p>Direct Benefits: Provides clarity for regulated entities.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$0	(c) \$0	
Direct Benefits	(b) \$0	(d) \$0	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A
(5) Indirect Costs & Benefits	<ul style="list-style-type: none"> • VDH is no longer able to calculate percent positivity for COVID-19 Indirect Costs: \$0 <p>Indirect Benefits: \$0</p> <ul style="list-style-type: none"> • VDH receives data in a more efficient and accessible manner, which results in an improved disease response and ability to mitigate spread and inform the public Indirect Costs: \$0 <p>Indirect Benefits: \$0</p>		
(6) Information Sources	N/A		
(7) Optional			

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> • The lists in 12VAC5-90 currently state “coronavirus, severe” which currently includes COVID-19 and is rapidly reportable. Direct Costs: Increased burden on reporting entities to provide reports within 24 hours rather than 3 days. <p>Direct Benefits: \$0</p>
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	<ul style="list-style-type: none"> <p>All COVID-19 test results (positive and negative) are required to be reported. Direct Costs: Increased burden on reporting entities to continue to report a large volume of negative test results, which is not in compliance with current federal law (CARES Act).</p> <p>Direct Benefits: VDH continues to be able to calculate percent positivity.</p> <p>Physicians and Medical Directors are to report hospitalization status and ICU admissions through the Emergency Department Care Coordination system. Direct Costs: \$0 – however, VDH has not been able to receive the data from this program in a meaningful manner to be able to report on COVID-19 hospitalizations to indicate severity of the disease.</p> <p>Direct Benefits: \$0</p> <p>All laboratories, including pharmacies that hold Clinical Laboratory Improvement Amendments Certificates of Waiver, shall report COVID-19 results. Direct Costs: Other entities that hold CLIA waivers may not believe they have an obligation to report, even though it is a requirement of their waiver.</p> <p>Direct Benefits: \$0</p> <p>Allows laboratories to use their own form or a computer generated report. Direct Costs: VDH isn't able to receive the records in a meaningful way and has to dedicate sufficient staff to be able to work with the reporter to get the record into the format needed.</p> <p>Direct Benefits: Reporting entities who do not have electronic laboratory reporting set up or who are not sending us reports in the format needed would still be able to submit the information in the format they have it in. In assessing the past 4 months of COVID-19 laboratory data, only 3% of records received were through a method other than ELR.</p> 	
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(2) Quantitative Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$0	(c) 0

Direct Benefits	(b) \$0	(d) 0	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A
(5) Indirect Costs & Benefits	No indirect costs or benefits anticipated.		
(6) Information Sources	N/A		
(7) Optional			

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> In light of clear statutory requirements for VDH to maintain the Disease Reporting and Control Regulations including the list of reportable diseases and the persons required to report there are no alternatives available. <p>Direct Costs: N/A</p> <p>Direct Benefits: N/A</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$0	(c) 0	
Direct Benefits	(b) \$0	(d) 0	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A
(5) Indirect Costs & Benefits	N/A		
(6) Information Sources			

(7) Optional	
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Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	No anticipated direct impact on local partners.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	No anticipated indirect impact on local partners.
(4) Information Sources	N/A
(5) Assistance	N/A
(6) Optional	

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs & Benefits	No anticipated direct impacts on families.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0

(3) Indirect Costs & Benefits	VDH data is more complete and readily available to inform families about COVID-19 cases in their communities.
(4) Information Sources	N/A
(5) Optional	

Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	Small laboratories or medical facilities required to report will benefit from changes related to reporting negative tests and having to report within 24 hours. These same entities might experience a slight increase in burden by no longer being able to submit their own form, but that is anticipated to be a one-time burden.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	No anticipated indirect costs or benefits to small businesses.
(4) Alternatives	No alternatives identified at this time.
(5) Information Sources	N/A
(6) Optional	

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
12VAC5-90	170	1	3	-2